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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,340	07/31/2000	Victor Pan	LIFE-009	5593

7590 05/19/2003

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EXAMINER

CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 05/19/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/630,340

Applicant(s)

PAN ET AL.

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to Applicants' amendment filed on March 5, 2003 and entered as Paper No. 9. Claims 1-22 are pending. Claims 1-10 are withdrawn from consideration as being directed to non-elected subject matter.

Claim Rejections - 35 USC § 112

1. Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19-22 recite "means for collecting reflectance data substantially as represented in Figure 6E". This phrase is indefinite because it unclear what Applicants are attempting to claim. Further, it is improper for the claims to refer to the figures in such as manner. In examining figure 6E, it appears that the content of the figure is the same as what has been incorporated into claim 11 - "wherein reflectance data is collected over a period of time...", thereby making claim 19 no different in scope than claim 11.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 11, 12, 14, 19, 20 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,084,660 to Shartle (hereinafter Shartle '660).

Shartle '660 teaches an automated meter useful in testing for the presence of a sufficient amount of sample on a test strip. The meter comprises a means for obtaining reflectance data via a LED illumination source 42a (visible light source) and a detector 42b. The light source illuminates the sample port 12. The detector measures reflected light. A signal is provided denoting the presence of the sample. This signal causes an actuator 48 to release bladder member 14 and move sample further down the test strip. See col. 6, line 54 – col. 7, line 33. In figure 4, the automatic meter is shown as it acts on a test strip 10.

Applicants' recitation of the period over which reflectance data is collected is considered to be the manner in which the means for collecting reflectance data operates. MPEP 2114 states that the manner of operating does not differentiate apparatus claims from the prior art, where the art teaches all the structural limitations claimed, citing *Ex parte Masham*, 2 USPQ2d 1647. Even if the limitation were given patentable weight, Shartle anticipates the claim. Shartle teaches that when sample is introduced at the sample application area, a reduction in the reflected light to the detector occurs, thereby triggering the release of the bladder. Thus, the detector, which collects the reflected light data, inherently detects reflected light prior to sample being present at the sample application zone and when sample is present. The detector

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would not sense a reduction in reflected light if the detector did not detect reflected light prior to sample being present.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 103 in view of the teachings of Shartle '660.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 13, 15-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shartle '660 in view of US Patent 5,674,699 to Saunders et al (hereinafter Saunders et al '699).

Shartle '660 is described in detail above; the reference fails to teach any particular wavelength to use in irradiating the test strip.

Saunders et al '699 teaches that chemicals/compounds specifically absorb light at certain wavelengths. Saunders et al '699 further teaches that the absorbances of many chemicals/compounds are known and that one of ordinary skill in the art can readily determine the wavelength at which a particular assay should be conducted to obtain maximum results. See col. 13, lines 1-29. Thus, it would have been obvious to one of ordinary skill in the art to use a wavelength suitable for reflecting light from the particular sample being deposited on the test strip in conducting the method of Shartle '660.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Shartle '660.

Response to Arguments

6. Applicant's arguments filed March 5, 2003 have been fully considered but they are not persuasive. Applicants argue that the Shartle reference does not teach that the reflectance data is collected over a period of time from before the test strip is introduced into the optical meter to after sample is applied to a sample application zone. The position of the Examiner is that this language involves how the means for collecting reflectance data operates and therefore does not impart patentability to the claims, since the structural elements of the claimed invention are essentially the same as those taught by Shartle. Even where the limitation is given patentable weight, the position of the Examiner is the limitation is indeed taught by Shartle. Shartle teaches that when sample is introduced into the sample application zone of the test strip, a reduction in reflected light occurs. The detector detects the reduction in light. The detector must detect reflected light prior to sample application in order for the detector to sense a reduction in reflected light due to the presence of sample on the test strip. Thus, the reference meets Applicants' new claim limitation.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to

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37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LaToya I. Cross
Examiner
Art Unit 1743

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May 17, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700